



NYU Shanghai Procedures for Human Subjects Research Protection

Section 12 Special Topics

12.4 Student Research

12.4.1 Human Subjects Research and Course Projects

Learning how to conduct ethical human subjects research is an important part of a student's educational experience. Research exercises that are designed as part of a course requirement for purposes of learning experience only and are **not** "designed to develop or contribute to generalizable knowledge" **do not require** IRB review and approval if all of the following conditions are true:

- Results of the research exercises are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes.
- Results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, publicly accessible blog, etc.).
- Research procedures present no more than minimal risk defined in section 1.
- Vulnerable populations are not targeted (e.g., children, pregnant women, fetuses, neonates, prisoners, mentally disabled persons or adults who lack the ability to consent or persons with diminished autonomy; please refer to section 7.4 and section 8 for definitions) and sensitive topics where the welfare of the individual requires special consideration (e.g., domestic violence) are not the focus.
- Data collected are recorded in such a manner that the subjects are not identifiable. When audio or video recordings are instrumental to the research exercise, the storage and cataloging of these materials does not contain identifying information. Video recordings and/or audio recordings are to be shared only in the context of classroom learning. If they are used or shown outside of the classroom, they then qualify as research and will require IRB approval.
- When appropriate, an informed consent process is in place.

In the event that a classroom research exercise yields results that a) warrants further study or b) the student would like to use the data for research purposes, the student must first contact the IRB before proceeding. The IRB will review the research to determine if the student might have some additional requirements in order to use the data or to continue the research for purposes other than classroom education; for example, possibly consenting or re-consenting subjects informing them of the new use.

Please note: If an individual conducts research without the appropriate IRB approval, it is possible that there would be a sanction in which the data could not be used. The IRB has the authority to determine whether the data collected without IRB approval can be used.

12.4.1.1 Responsibilities of the Course Instructor

The course instructor is responsible for communicating to the students the ethics of human subjects research, for ensuring the protection of human subjects (including a process is in place for obtaining

voluntary informed consent from research subjects when appropriate), and for monitoring the students' progress.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should:

- Understand the elements of informed consent;
- Develop appropriate consent documents;
- Plan appropriate strategies for recruiting subjects;
- Identify and minimize potential risks to subjects;
- Assess the risk-benefit ratio for the project;
- Establish and maintain strict guidelines for protecting privacy and confidentiality; and
- In the case of research activities that go beyond classroom instruction, allow sufficient time for IRB review (if necessary) and completion of the project.

In making a determination of whether or not a class research project requires IRB review, the instructor is encouraged to visit our website (<https://research.shanghai.nyu.edu/resources/human-subjects>) for more information or contact the IRB office (RCOinfo@nyu.edu) for assistance.

12.4.1.2 Individual Research Projects Conducted by Students

Independent study projects, senior theses, undergraduate research projects, and advanced degree research, and similar exercises involving human subjects research must be independently submitted for IRB review. It is important to keep in mind that any human subjects research activity that will ultimately contribute to part or all of a thesis, dissertation, or other type of publication or presentation must go through the IRB review process prior to enrolling subjects and collecting data. IRB review/approval cannot occur after a study has begun.

Students and advisors should contact the IRB Office (RCOinfo@nyu.edu) with any questions.

12.4.2 Independent Study, Theses and Dissertations

Those research activities that are considered to meet the federal definition of human subjects research must be independently submitted to the IRB by the student-investigator. When students conduct research as part of a course of study, the faculty member is still ultimately responsible for the protection of the subjects, even if the student is the investigator and actually conducts the project. Faculty advisors assume the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

At NYU Shanghai, students may not serve as principal investigators. They must have a faculty sponsor who fulfills the principal investigator eligibility criteria (please refer to section 11.1 "Investigator Classifications" of the NYU Shanghai Procedures for Human Subjects Research Protection), and who will serve as principal investigator and faculty advisor on the study.

12.4.2.1 Roles and Responsibilities of the Faculty Advisor

What is the faculty advisor's role in student-conducted research?

The faculty advisor shares with the student the responsibility for the ethical conduct of the research. The advisor is responsible for ensuring that research activities involving human subjects are

reviewed and approved by the NYU Shanghai IRB before they are initiated. The faculty advisor is expected to take an active role in student research activities and provide supervision for the duration of the project. The faculty advisor is responsible for all research activities and must review, approve and sign the submission to the IRB.

What are the responsibilities of the faculty advisor in student-conducted research?

- 1. Be informed.** Contact the IRB Office to discuss policies and procedures for obtaining IRB review before the initiation of research activities. Faculty advisors are expected to be familiar with institutional requirements for the conduct of human subjects research. Familiarize yourself with the IRB website.
- 2. Complete the CITI training** for human subjects research. Faculty advisors are expected to be familiar with ethical and regulatory requirements.
- 3. Know what must be reviewed.** Determine when an undergraduate or graduate student project constitutes research with human subjects and requires review by the IRB Office and/or the IRB. If you are unsure about whether or not a planned activity constitutes research with human subjects it is your responsibility to contact the IRB Office for guidance.
- 4. Assist students with protocol submission.** When proposed activities constitute research with human subjects, it is the responsibility of the faculty advisor to assist students in preparing and reviewing materials to be submitted to the NYU Shanghai IRB. Faculty advisors are responsible for reviewing the scientific integrity of the project, including evaluating the scientific rigor and merit of the study.
- 5. Educate students** on the role of the NYU Shanghai IRB and the importance of research review. Students must complete the CITI training for human subjects research before submitting an application to the IRB.
- 6. Maintain ethical standards.** Faculty advisors ensure that projects are conducted to the highest ethical standards and that students understand and implement these ethical standards in the conduct of their research.
- 7. Help students navigate the IRB process.** Faculty advisors contact the IRB Office to determine what the requirements are for submission to the IRB and help students understand the NYU Shanghai IRB process.
- 8. Take an active role** in the IRB review process and assist students when presented with questions and comments from the IRB and/or IRB staff.
- 9. Meet regularly with the student** to review project, progress and any issues.
- 10. Ensure data security and retention** as described in the approved IRB protocol.
- 11. Oversee changes.** Ensure that before a change is implemented to an approved protocol, the change is approved by the IRB. All changes must be reviewed by the faculty advisor before submission to the IRB.
- 12. Report any unanticipated problems** or other research-related problems to the IRB as soon as possible.
- 13. Ensure that continuing review requirements** are satisfied when applicable.
- 14. Ensure that the study is closed** at the conclusion of the study.